



## MEMORANDUM

**To:** Members and Staff, Subcommittee on Oversight and Investigations

**From:** Majority Committee Staff

**Re:** Hearing on “Antimicrobial Resistance: Examining an Emerging Public Health Threat”

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On Friday, April 28, 2023, at 9:00 a.m. (ET) in 2123 Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled, “Antimicrobial Resistance: Examining an Emerging Public Health Threat.”

### I. WITNESSES

- Amanda Jezek, Senior Vice President, Public Policy and Government Relations, Infectious Diseases Society of America
- Kevin Outterson, Professor of Law and Executive Director of CARB-X, Boston University
- Mary Denigan-Macauley, Director, Health Care, U.S. Government Accountability Office
- Amy J. Mathers, Associate Professor, Medicine: Infectious Diseases and International Health, University of Virginia School of Medicine

### II. OVERVIEW

Antimicrobial resistance (AMR) is a significant and growing public health concern that threatens the effectiveness of our current arsenal of antibiotics and other antimicrobial drugs. In 2019, an estimated 1.27 million deaths globally were directly attributable to drug resistance, and in the United States, more than 2.8 million antibiotic-resistant infections occur each year, resulting in more than 35,000 deaths.<sup>1</sup> The World Health Organization has declared AMR “one of the top 10 global public health threats facing humanity.”<sup>2</sup> AMR is not only a serious health concern but

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<sup>1</sup> Antimicrobial Resistance Collaborators, *Global Burden of Bacterial Antimicrobial Resistance in 2019: A Systematic Analysis*, 399 Lancet 629 (2022), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02724-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext); Centers for Disease Control and Prevention, Antibiotic Resistance Threats in the United States (2019), <https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf>.

<sup>2</sup> World Health Org., *Antimicrobial Resistance* (Nov. 17, 2021), <https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance>.

also a costly one. A Centers for Disease Control and Prevention (CDC) study found treating multi-drug resistant pathogens costs the U.S. health care system \$4.6 billion annually.<sup>3</sup>

This hearing will provide an opportunity to gain a better understanding of the ongoing concerns about AMR, the specific factors that may contribute to its rise, current public and private sector efforts to combat AMR, and any viable, effective solutions available to address the issue. The hearing will explore the potential consequences of inaction, the global impact of AMR, and the range of already existing and proposed programs, research efforts, and alternative therapies, such as phage therapy, that could be implemented to combat this growing public health threat.

### III. BACKGROUND

AMR is a serious public health concern that arises when microorganisms such as bacteria, viruses, fungi, and parasites develop the ability to resist the effects of drugs. Through physiological and biochemical changes, these microbes can develop defense mechanisms against drugs, which can compromise the treatment of common infections and pose a significant risk to health care, food production, and life expectancy.<sup>4</sup> For example, as more pathogens become resistant to drugs, more people are at risk to become susceptible to complications such as sepsis. This can make routine treatments, such as joint replacements, cesarean sections, organ transplants, dialysis, and chemotherapy, riskier.

#### *The rise in AMR*

AMR is a naturally occurring process but is considered a growing threat primarily due to the societal overuse of antimicrobials, including antibiotics. Antimicrobials, such as antibiotics and fungicides, are used in a variety of sectors, including medical care, animal health, and agriculture.

The rise in drug-resistant infections has placed a heavy burden on the nation's health care system. While antibiotics are important and powerful medicines that have saved countless lives, the overuse of antibiotics is a contributing factor to the emergence of antimicrobial resistance. Data from the CDC suggests that approximately 30 percent of antibiotics prescribed in medical settings are unnecessary and often prescribed for infections that do not require antibiotics.<sup>5</sup> For example, during the COVID-19 pandemic, antibiotics were frequently prescribed even though they are ineffective against viral infections. This overuse of antibiotics can lead to the spread of antimicrobial resistant pathogens within and between health care facilities, causing infections in patients and potentially spreading to the community and the environment.<sup>6</sup>

Antimicrobial drugs are also widely used in animal agriculture and veterinary medicine, often to treat disease in food-producing animals.<sup>7</sup> The use of antibiotics in animal care may

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<sup>3</sup> Centers for Disease Control and Prevention, *National Infection & Death Estimates for Antimicrobial Resistance*, <https://www.cdc.gov/drugresistance/national-estimates.html>.

<sup>4</sup> Antibiotic Resistance Threats in the United States (2019), *supra* note 1, at 3.

<sup>5</sup> *Id.* at 18.

<sup>6</sup> Centers for Disease Control and Prevention, *COVID-19 & Antimicrobial Resistance*, <https://www.cdc.gov/drugresistance/covid19.html>.

<sup>7</sup> National Academies of Sciences, Engineering, and Medicine, *Combating Antimicrobial Resistance and Protecting the Miracle of Modern Medicine* (2022), <http://nap.nationalacademies.org/26350>, at 35.

contribute to the emergence of resistant bacteria that may be transferred directly or indirectly, through consumption of food or other industrial processes, to other species, including humans. Various efforts are underway across the federal government and animal health sector to implement best practices in antimicrobial stewardship in veterinary settings, including the implementation of FDA's guidance on transitioning medically important antimicrobial drugs intended for use in food-producing animals from over-the-counter status to prescription-only.<sup>8</sup>

Globally and in the U.S., antimicrobials, particularly antifungals, are a relatively inexpensive way to control plant diseases and protect agricultural crops. Their use as pesticides may hasten the development and spread of drug-resistant pathogens by contaminating surrounding soil and water, which can spread to nearby lakes and rivers.<sup>9</sup>

Increased antimicrobial resistance is compounded by misaligned market incentives and subsequently, a broken therapeutic development pipeline. Despite increased demand, drug manufacturers have scaled back or cut antibiotic research due to development challenges, with 78 percent of major drug companies having done so since 1990.<sup>10</sup> Between 1962 and 2000, no new major classes of antibiotics were approved to treat common and deadly Gram-negative infections.<sup>11</sup>

#### IV. KEY QUESTIONS

The hearing may include discussion around the following key questions:

- Why is AMR considered a public health threat, and what are the potential consequences of inaction?
- What specific factors have contributed to the rise of AMR, and how have these factors interacted with each other to create a complex and challenging problem?
- How has the COVID-19 pandemic affected the issue of AMR, and what lessons can be learned from this experience to inform future efforts to address AMR?
- What are the current public and private sector efforts to combat AMR, and how successful have they been?

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<sup>8</sup> U.S. Food & Drug Admin., Center for Veterinary Medicine, #263 Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter: Guidance for Industry (2021), <https://www.fda.gov/media/130610/download>.

<sup>9</sup> Antibiotic Resistance Threats in the United States (2019), *supra* note 1, at 28.

<sup>10</sup> Jim O'Neill, Tackling Drug-Resistant Infections Globally: Final Report and Recommendations (2016), [https://amr-review.org/sites/default/files/160518\\_Final%20paper\\_with%20cover.pdf](https://amr-review.org/sites/default/files/160518_Final%20paper_with%20cover.pdf), at 52; Antibiotic Resistance Threats in the United States (2019), *supra* note 1, at 34.

<sup>11</sup> Antibiotic Resistance Threats in the United States (2019), *supra* note 1, at 34.

- What solutions are currently available to combat the growing problem of AMR, and how effective have these solutions been in practice? Specifically, what are the benefits and limitations of already existing approaches?
- What are phage therapy, monoclonal antibodies, and immune based therapies and how do they work? What are the potential benefits and limitations as treatment for resistant infections, and how might it be integrated into broader efforts to combat AMR?

## **V. STAFF CONTACTS**

If you have any questions regarding the hearing, please contact Gavin Proffitt or Joanne Thomas with the Subcommittee on Oversight and Investigations Majority staff at (202) 225-3641.